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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,832	07/01/2003	Harald Stein	086035-000000US	3864

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
YAO, LEI	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,832	STEIN ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-30* is/are pending in the application.

4a) Of the above claim(s) *10,12-14 and 19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-9,11,15-17,29-30* is/are rejected.

7)☐ Claim(s) *6,7 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on 11/14/05 in response to the previous Non-Final Office Action (2/24/05) is acknowledged and has been entered.

Claims 1and 6-30 are pending. Claims 2-5 have been cancelled. Claims 1 and 16-18 have been amended. Claims 10, 12-14, 19-28 have been withdrawn for non-elected invention. Claims 1, 6-9, 11, 15-18 and 29-30 are under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

The following office action contains NEW GROUNDS of rejection.

Rejections or Objection Withdrawn

1. Objection of Specification because the sections (b), (c), (f), (g), and (i) are either missing or not correctly stated in the specification is withdrawn in view of the amendment.

2. Objection of claims 1-2, 4-8 and 16-17 because of typographical error as "characterized" is withdrawn in view of the amendment of the claims.

3. The rejection of claims 7, 15-18 under *35 USC § 112, 1st paragraph* as failing to comply with the enablement requirement is withdrawn in view of the applicant argument and submitted document (9/5/05) for deposition of cell line DSZ1.

4. The rejection of claim 1 under *35 USC § 102(b),* as being anticipated by Gravekamp et al., (Infec and Immu, vol 64, page 3572-3583) is withdrawn in view of the amendment of the claims and the disclosure of the art.

5. The rejections of claims 5 and 6 under *35 USC § 102(b),* as being anticipated by anticipated by Lemke et al., (US Patent NO: 6033876) and/ or Mohler et al., (US Patent Application Publication NO: 20020064527) is withdrawn in view of the cancellation and amendment of the claims.

Response to Arguments

1. ***Rejection under 35 USC § 112 2nd* Paragraph**

The rejection of claim 1 under 35 U.S.C. 112 2nd A and B as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons of record in the prior Office Action (2/24/05, page 4) and made again for the newly amended claim 1.

The response and amendment filed 9/6//05 have been carefully considered but is deemed not to be persuasive because the term" at least two spatially separated position on a cell bound or soluble target molecule" and term "enters into interactions with cell-bound or soluble target molecule" are still not clear. It is not clear what they are referring to. If the claim encompasses an antigen, soluble or cell bound CD30 molecule, having two separated core amino acid sequences CEPDY, which allow an antibody to bind, applicant should amend the claim clearly stating invention.

2. ***Rejection under 35 USC § 112 1st* Paragraph**

The rejection of claims 1, 8, 9, 11, 15-16 and 29-30 under 35 U.S.C. 112 1st failing to comply with the written description requirement because he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record in the prior Office Action (2/24/05, page 4) and made again for the newly amended claims 1 and 15-17.

The response filed 9/6/05 has been carefully considered but is deemed not to be persuasive. The response states that applicants have amended claims to recite the cell-bound or soluble target molecule is CD30 and the reagent binds to an epitope with a core sequence CEPDY and response further states that the claimed reagent are compound comprising a protein structure capable of biding to an epitope with a core sequence of CEPDY. The response also states that the core sequence of the epitope provides structural feature possessed by member of the claimed genus. In response to this argument, the structural feature of the CEPDY binding molecule would be significantly different among an

antibody, a T-cell receptor and other reagents although they all could bind to a core sequence of CEPDY. The claimed structural attribute of the core sequence CEPDY on CD30 molecule to the reagents does not provide sufficient evidence and structural characteristics of the genus for binding to the core sequence CEPDY except the reagent might give a binding ability to the sequence of CEPDY. One skilled in the art would know that the binding to an epitope having a specific amino acid sequence comprising CEPDY is not only due to the amino acid sequence of the epitope, the negative/positive charges of the epitope, the adding the sugar or glycosylation on the peptide, or the secondary structure of the sequence all play an important role in the binding process and consequence. One skilled in the art would know that the structure and sequence of an antibody to an epitope of amino acid sequence CEPDY is different from the structure of a T-Cell receptor or a hybrid scFv/sc TCR fragment, or any other reagent. The specification only provides one species of monoclonal antibody for CD30, which specifically bind to sequence of "DCRKQ**CEPDY**YLD and GDCRKQ**CEPDY**YL" of CD30 by epitope mapping and **CEPDY** as a core sequence, not any other protein or reagent to bind to the core sequence. Therefore, only the antibody to the epitope **CEPDY** of CD30, produced by a cell, DSM ACC2548, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

3. ***Rejection under 35 USC § 102(b)***

The rejection of claims 1, 15, 29-30 under 35 U.S.C. 102(b) as being anticipated by Lemke et al., (US Patent NO: 6033876) is maintained for the reasons of record in the prior Office Action (2/24/05, page 10) and made again for the newly amended claims 1 and 15.

The response filed 9/6/05 has been carefully considered but is deemed not to be persuasive. The response states that Lemke et al., do not disclose a reagent that interacts with at least two spatially separated positions on CD30 or a reagent, which binds an epitope with a core sequence CEPDY. In response to this argument, again, although the patentability of the presently claimed invention, as compared to the state of the art, is further evidenced by the unexpected ability of the claimed reagent to binds to at least two spatially separate position on the target molecule, as the Applicants argued, there are not evidences to show that the antibodies of the state and antibodies disclosed by Lemke et al., have

no ability to bind to the two spatially separate position on the target molecule. One skilled in the art would know antigen binding fragments developed using a specific antigen, such as CD30, would include all the possible antigen binding fragments, which would likely interact with any possible epitope of the antigen comprising the CEDPY on CD30. Since the Applicants do not provide any evidence indicating the antibodies of Lemke et al., do not bind to the two spatial epitope, CEPDY, of CD30 in response to the office action, the antibodies of Lemke et al., still read on the claimed reagent comprising the antibody to the epitope of CD30.

4. ***Rejection under 35 USC § 102(b)***

The rejection of claims 1, 8-9 and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Francisco et al., (US Patent Application Publication NO: 20040018194) is maintained for the reasons of record in the prior Office Action (2/24/05, page 4) and made again for the newly amended claims 15-16.

The response filed 9/6/05 has been carefully considered but is deemed not to be persuasive. The response states that Francisco et al., do not disclose a reagent that interacts with at least two spatially separated positions on CD30 or a reagent, which binds an epitope with a core sequence CEPDY. In response to this argument, again, although the patentability of the presently claimed invention, as compared to the state of the art, is further evidenced by the unexpected ability of the claimed reagent to binds to at least two spatially separate position on the target molecule, as the Applicants argued, there are not evidences to show that the antibodies of the state and antibodies disclosed by Francisco et al., have no ability to bind to the two spatially separate position on the target molecule. One skilled in the art would know antigen binding fragments developed using a specific antigen, such as CD30, would include all the possible antigen binding fragments, which would likely interact with any possible epitope of the antigen comprising the CEDPY on CD30. Since Applicants do not provide any evidence indicating the antibodies of Francisco et al., do not bind to the two spatial epitope, CEPDY, of CD30 in response to the office action, the antibodies of Francisco et al., still read on the claimed reagent comprising the antibody to the epitope of CD30. Francisco et al., also disclose that

anti-CD30 antibodies are fused to proteins comprising a pro-drug converting enzyme, which anticipate claims 8-9 because the claims are broadly drawn to any toxic protein or enzyme or proenzyme linked to the claimed antibody.

5. ***Rejection under 35 USC § 103***

The rejection of claims 1, 8-9 and 11 under 35 U.S.C. 103 as unpatentable over Lemke et al., in view of Deonarain et al., (Br J Cancer, vol 70 page 786-94, 1994) is maintained for the reasons of record in the prior Office Action.

The response filed 9/6/05 has been carefully considered but is deemed not to be persuasive. The response states that Lemke et al., do not disclose a reagent that interacts with at least two spatially separated positions on CD30 or a reagent, which binds an epitope with a core sequence CEPDY. The response also states that Deonarian et al., does nothing to remedy the deficiencies of Lemke. In response to this argument, as discussed above, the Applicants do not provide any evidence indicating the antibodies of Lemke et al., do not bind to epitope, CEPDY, of CD30 in response to the Office action, therefore, the antibodies of Lemke et al., still read on the claimed reagent comprising the antibody. Deonarian et al., teach that an enzyme of phosphodiesterases is linked to anti-tumor antibody or antibody fragments for cancer therapy, It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teaching of Lemke et al., with the teaching of Deonarain et al., to make anti-CD30 antibody linked to an enzyme of phosphodiesterases. One of ordinary skill in the art would have been motivated to use the teachings of Lemke et al., and Deonarain et al., by linking the antibody of CD30 with the enzyme for the benefit of cancer treatment because Denarain et al., have shown that a antibody linked to the enzyme of phosphodiesterases is cytotoxic to cells, which does suggest AND motivate one skilled in the art with a reasonable expectation of success to link the anti-CD30 antibody with the enzyme of phosphodiesterases to target the CD30 expressing molecule and treating CD30-postivie disorder.

The Following is a New Ground of Rejection or Objections

Claim Objections

Claims 6-7 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

NO claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LY

KAREN A. CANELLA PH.D
PRIMARY EXAMINER

Lei Yao, Ph.D.
Examiner
Art Unit 1642